**Conclusions:** Children with UC who received GLM q4w maintenance showed continued clinical benefit through week 126 in this open-label study. Trough values with maintenance SC GLM treatment q4w through week 126 were consistent over the extended treatment time. Antibodies to GLM were observed in a minority of patients and generally were low-titer and non-neutralising. Almost half of the patients in the LTE completed home administration by self or caregiver after week 18.These findings are consistent with the established clinical benefit and safety profile of golimumab in the adult UC population.

## P397

## Effectiveness of vedolizumab (VDZ) for the induction of remission in inflammatory bowel disease (IBD): Results from the Spanish Eneida Registry

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**Background:** The aims of this study were (1) to assess the effectiveness of VDZ in IBD patients and (2) to identify factors associated with the response to the treatment.

**Methods:** IBD patients [Crohn's disease (CD) and ulcerative colitis (UC)] that had received at least 3-induction doses with VDZ in the ENEIDA registry—a large prospectively maintained Spanish database promoted by the Spanish Working Group in Crohn's and Colitis (GETECCU) were included. Patients treated with VDZ due to active IBD [Partial Mayo Score (PMS) ≥2 or Harvey-Bradshaw (HBI) >4] were included. Short-term response was evaluated at week 14. Clinical response was defined as reduction in the PMS ≥3 points and a decrease of at least 30% from baseline, with a decrease of ≥1 point on the rectal bleeding subscale. For luminal CD, partial response was defined as a decrease in the HBI ≥3 points without reaching remission. Severity of the disease was rated by PMS or HBI. The variables associated with short-term remission were identified by logistic regression model.

**Results:** A total of 274 patients were included; 144 (52%) of them had CD (Table 1).

**Table 1. Characteristics of the study population based on clinical remission at week 14.**

| Variable | Remission | No remission | p |
|---|---|---|---|
| Age, year (IQR) | 46 (34-59) | 41 (35-53) | 0.05 |
| Time of evolution of the disease, months (IQR) | 134 (60-181) | 119 (53-193) | N.S. |
| Female gender, n (%) | 74 (55.6) | 88 (62.4) | N.S. |
| Crohn's disease, n (%) | 68 (51) | 76 (54) | N.S. |
| Anti-TNF-naive, n (%) | 14 (10.5) | 3 (2.1) | <0.01 |
| One anti-TNF before vedolizumab, n (%) | 31 (23.3) | 29 (20.6) | |
| At least two anti-TNFs before vedolizumab, n (%) | 88 (66.2) | 109 (77.3) | |
| Anaemia, n (%) | 652 (39) | 63 (44.7) | N.S. |
| Severe disease at induction with vedolizumab , n(%) | 13 (9.8) | 34 (24.5) | <0.01 |
| Previous surgery, n (%) | 37 (27.8) | 56 (39.7) | <0.05 |
| Concommitant immunomodulators, n (%) | 91 (68.4) | 102 (72.3) | N.S. |
| Steroids during induction, n (%) | 77 (58.3) | 87 (62.6) | N.S. |
| Smoking habit, n (%) | 22 (16.5) | 22 (15.6) | N.S. |
| Extraintesintal manifestations, n (%) | 55 (42.3) | 49 (36.6) | N.S. |

A total of 257 patients (94%) had been refractory to biologic agents before starting VDZ: 60 patients (22%) had previously failed to a biologic agent, and 197 (71%) to at least 2 anti-TNF drugs. After the induction doses (week 14), 66% of patients responded to the treatment (48% achieved remission and 18% partial response). The proportion of patients that reached remission was significantly higher among those naïve to anti-TNF drugs vs. those receiving VDZ after one anti-TNF vs. those receiving VDZ after at least two anti-TNFs (82 vs. 52 vs. 45%, respectively, $p < 0.05$). In addition, remission at week 14 was significantly lower among patients with severe disease at VDZ starting in comparison with those with moderate or mild disease (28 vs. 40. vs. 70%, respectively, $p < 0.001$). In the multivariate analysis, to have CD (vs. UC), the number of previous anti-TNF treatments and the severity of the disease were associated with lower probability of achieving remission at week 14 (Table 2).

**Table 2. Variables associated with clinical remission at week 14.**

| Variable | Odds ratio | 95% confidence interval |
|---|---|---|
| Crohn's disease vs. ulcerative colitis | 0.5 | 0.2-0.9 |
| Experienced with anti-TNF treatment | | |
| Naïve vs. 2 or more anti-TNFs | 5.3 | 1.4-20.4 |
| 1 anti-TNF vs. 2 or more anti-TNFs | 1.3 | 0.7-2.5 |
| Severity of the disease at induction | | |
| Mild vs. severe disease | 9 | 3.7-21.4 |
| Moderate vs. severe disease | 2.7 | 1.2-6 |

**Conclusions:** Approximately 2/3 of patients respond to VDZ treatment, and 1/2 reach remission, even in a refractory IBD cohort. To have CD (instead of UC), previous failure to at least 2 anti-TNF drugs and severe disease activity at VDZ starting were significantly associated with lower probability of remission at week 14.

## P398

## Cannabis induces clinical and endoscopic improvement in moderately active ulcerative colitis (UC)

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**Background:** Cannabis is frequently used by patients with UC, although it was never investigated in a controlled trial. We aimed to assess the effects of Cannabis in moderately active UC in a randomised placebo controlled trial.

**Methods:** Patients with UC who did not respond to conventional medical treatment were randomised to receive two cigarettes of cannabis or placebo daily. Each cigarette contained 0.5 g of cannabis, corresponding to 11.5 mg THC. The placebo contained cannabis leaves from which THC was extracted. Disease activity (DAI), endoscopic findings and laboratory tests were assessed before and after 8 weeks of treatment. All other medication remained unchanged.

**Results:** Twenty-eight patients completed the study, mean age 33 (20–61), 17 males. The colitis was extended in 11 and left sided in 17 patients. During treatment the DAI decreased from 10 ± 3 to 4 ± 3.2 and from 10 ± 2.7 to 8 ± 2 ($p < 0.01$), while the Mayo endoscopic score decreased from a median of 2 (IQR = 2–2.5) to 1 (IQR 0–2) ($p = 0.01$) and from 2 (IQR = 2–2) to 2 (IQR 1.25–2) ($p = 0.059$) in the THC and placebo groups, respectively. The mean CRP changed from 0.8 ± 0.9 to 0.7 ± 1.2 and from 1.8 ± 1.9 to 1 ± 1.6 (mg/dl) ($p = 0.5$), whereas faecal Calprotectin changed from 135 ± 113 to 115 ± 103 and from 226 ± 100 to 229 ± 230 (mg/dl)in the THC and placebo groups, respectively ($p = 0.7$). No serious side effects were observed.

**Conclusions:** Tetrahydrocannabinol-rich cannabis is safe and can induce clinical as well as endoscopic improvement in moderately active UC.

## P399

## Vedolizumab therapy results in reduced hospitalisation and steroid use over 1-year: Results from the Scottish vedolizumab consortium

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**Background:** Whilst the GEMINI trials and an increasing body of real-world data have demonstrated the effectiveness and safety of vedolizumab (VDZ) in IBD, there are limited available data about the effect on hospitalisations and steroid use. Our aim was to address this in a large real-world cohort of IBD patients from across Scotland.

**Methods:** A multicentre retrospective cohort analysis of medical records was carried out at 7 Scottish healthcare trusts. Our primary outcomes were hospitalisation rates and overall steroid use in patients remaining on VDZ. Secondary outcomes were safety and intention to treat steroid free remission rates / mucosal healing in patients with active disease. All data were prospectively collected as part of routine clinical care. Baseline demographics, clinical severity scores (HBI or Partial Mayo), faecal calprotectin (FC), endoscopy, and radiology at 3, 6, and 12 months was recorded where available. Active disease was defined as endoscopic or radiographic evidence of disease or FC >200 µg/g. Clinical remission was defined as HBI<5 or Partial Mayo <2. Biochemical remission was defined as FC <200 µg/g. Mucosal healing was determined radiologically when endoscopy was not possible.

**Results:** A total of 340 (137 UC and 203 CD) patients were included in the primary analysis. Hospitalisation rates per patient-year were 0.60, 0.67, 0.36, and 0.16 at baseline, 3, 6, and 12 months of treatment respectively. Total number of hospitalisations reduced by 52.5% from 204 (12 months prior to VDZ) to 97 (12 months after VDZ). Proportion of patients on concomitant steroids reduced from 39.7% to 16.7% ($n = 332$), 8.1% ($n = 270$), 9.3% ($n = 194$) at 3, 6 and 12 months respectively. In patients with active CD ($n = 153$, 75.4%) steroid free clinical and steroid free biochemical remission rates were; 54.4% and 30.2% at 3 months; 47.7% and 32.1% at 6 months; 28.6% and 33.9% at 12 months. In patients with active UC ($n = 112$, 81.8%) steroid free clinical and steroid free biochemical remission rates were; 57.4% and 40.9% at 3 months; 51.6% and 39.1% at 6 months; 37.5% and 41.2% at 12 months. Cumulative mucosal healing for CD and UC was 46.3% ($n = 54$) and 44.4% ($n = 45$) by 12 months respectively. Our cohort received >2066 VDZ infusions, 2 (0.6%) patients developed infusion reactions, 9 (2.6%) patients developed serious infections and 17 (5.0%) serious adverse events.

**Conclusions:** VDZ is associated with reduced hospitalisation and steroid use. Steroid free remission rates, mucosal healing and safety profile were in keeping with the published literature.